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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/727,287 | 12/03/2003 | Scott W. Sanders | 480062001800 | 4663 |
| 25224 | 7590 | 09/22/2005 | EXAMINER | |
| MORRISON & FOERSTER, LLP. 555 WEST FIFTH STREET SUITE 3500 LOS ANGELES, CA 90013-1024 | | | AHMED, AAMER S | |
| | | ART UNIT | PAPER NUMBER | 3763 |

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|------------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/727,287 | SANDERS, SCOTT W. |
| | Examiner | Art Unit Aamer S. Ahmed 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8, 13, 16 and 19-24 is/are rejected.
- 7) Claim(s) 20 is/are objected to.
- 8) Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12/03/2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/3/03; 7/2705</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Claims 9-12, 14-15, and 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 27, 2005.

Furthermore applicant's response that claims 1, 13, 16 and 21 are generic claims is accepted.

Specification

The disclosure is objected to because of the following informalities: line 5 on page 2 contains missing text, it is suggested that the term "of" be inserted between the terms "variety" and "subcutaneous".

Appropriate correction is required.

Claim 24 is objected to because of the following informalities: the phrase "when the catheter aligned with" is unclear, it is suggested that the phrase be rewritten as "when the catheter is aligned with". Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 13, 16, and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cai et al U.S. Patent Number 5,562,618. As to claim 1, Cai et al discloses an implantable port (20) comprising a housing (22) comprising a fluid chamber (40) and an access aperture (58) in

fluid communication with the fluid chamber (40), wherein the access aperture (58) is covered by a septum (48); a port stem (84) extending from the housing (22), wherein the port stem (84) has an inner lumen (34) forming a channel in fluid communication with the fluid chamber (40); and a marking (100) for providing guidance to a user for placement of a catheter over the port stem (84), wherein the marking (100) is located on the port stem (84) and a proximal end of the port stem, see figures 1, 3 and 8; and wherein the marking (100) is positioned on the port stem (84) such that when the catheter (24) is aligned with the marking is compressed by the locking sleeve (102), the proximal end of the catheter (24) does not abut a housing (22) of the access port (20), (col. 8 line 55 and col. 6 line 60).

Furthermore as to claim 13, Cai et al ('618) teaches that the implantable access port (20) is capable of being implanted beneath the skin of a patient (col. 4 line 34), the access port (20) enabling repeated, non-destructive fluid communication between the tip of a hypodermic needle piercing the skin of the patient and the proximal end of a lumen within a catheter implanted in the body of the patient coupled to the access port (col. 4 line 61); the access port (20) comprising an outlet stem (84) extending from a housing (22) configured at a distal end to receive the proximal end of the catheter (24) the stem (84) enclosing a stem channel (34) extending between a proximal end and distal end, wherein the stem channel (34) is in fluid communication with a cavity (40) in the housing (22); and a marking (100) positioned on an outer surface of the outlet stem (84), wherein the marking (100) is located between the proximal end and distal end of the outlet stem (84), and wherein the marking (84) is configured to provide a visual reference for the placement of the catheter, see figures 1, 3 and 8.

Moreover, as to claims 16 and 19-20, Cai et al ('618) describes a method of making an access port having a port stem marking (100) comprising; fabricating an implantable access port (20) capable of being implanted beneath the skin of the patient (col. 4 line 34), the access port comprising an outlet stem (84) extending from a housing (22) of the access port (20), configured at a distal end to receive the proximal end of the catheter (24), the stem (84) enclosing a stem channel (34) extending between a proximal end and the distal end, wherein the stem channel (34) is in fluid communication with a cavity (40) in the housing (22); and providing a marking (100) on the outlet stem (84), wherein the marking (100) is located between the proximal end and distal end of the outlet stem (84). Cai et al ('618) further teaches that the marking (100) is placed on the port stem (84) while taking into account the amounts of sliding of the catheter (24) when a locking sleeve (102) is placed over the catheter (24) and the catheter (24) when aligned with the marking (100) is compressed by a locking sleeve (102) (col. 6 line 60), a proximal end of the catheter (24) does not abut the housing (22).

In addition as to claims 21-24, Cai et al ('618) discloses a method connecting a catheter to an access port during implantation of the access port comprising, inserting a port stem (84) of the access port (20) into the proximal end of the catheter (24); and adjusting the position of the catheter on the port stem 984) such that the proximal end of the catheter (24) is aligned with a marking (100) on the port stem (84), wherein the marking (100) is positioned on the port stem (84) as a visual reference for a securing connection between the catheter and the access port (20); and wherein the location of the marking (100) takes into account the amounts of sliding of the catheter (24) when the locking sleeve (102) is placed over the catheter; and wherein the marking (100) is positioned on the port stem (84) such that when the catheter (24) is aligned with the

marking is compressed by the locking sleeve (102), the proximal end of the catheter (24) does not abut a housing (22) of the access port (20), (col. 8 line 55 and col. 6 line 60).

Thus Cai et al ('614) reasonably appears to teach and disclose every element of claims 1, 13, 16, and 19-24 and therefore anticipates these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al ('618). Cai et al ('618) meets the claims limitations as described above in reference to claim 1 but fails to include that the marking comprise an ink contrast agent, a ribbon, a metallic ribbon or a shrink-wrap plastic.

Applicant has not disclosed that these specific components solve a state problem or are for any particular purpose. The instant specification does state that in general the marking does facilitate visualization for proper attachment of a catheter to the port stem. However, the

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specification does not indicate that these particular components as a marking are needed to the exclusion of other or similar forms of port stem markings. There is no disclosure that the claimed forms of markings are needed to perform this function and that the other form of markings would not perform equally well.

Therefore it appears that the port stem marker as described by Cai et al or any form of port stem marker would perform equally well. Accordingly, the use of these forms on markings on the port stem is deemed to be an obvious design consideration, which fails to patentably distinguish over the prior art of Cai et al ('618).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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US 5632729 A Cai; Qingsheng et al.
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US 6468252 B1 Sanfilippo, II; Dominic J.
US 4444185 A Shugar; Martin A.
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US 6484724 B1 Sloan; Ian Alexander
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| US 5399168 A | Wadsworth, Jr.; Daniel C. et al. |
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| US 4963133 A | Whipple; Gary R. |
| US 4772270 A | Wiita; Thomas A. et al. |
| US 5769814 A | Wijay; Bandula |
| US 5766211 A | Wood; Jan et al. |
| US 6913609 B2 | Yencho; Stephen A. et al. |
| US 5129891 A | Young; Thomas M. |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.



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